REMARKS

In this Amendment, all claims previously pending have been canceled, and claims 110-142 are substituted therefore.

New claims 110-125 are drawn to methods of diagnosing prostate cancer, new claims 126-141 are drawn to methods of diagnosing liver cancer, and new claim 142 is drawn to a method of diagnosing prostate cancer or liver cancer. The claims are supported by the specification as follows.

New independent claims 110 and 126 are supported by, for example, original claims 35, 36, and 46.

New claims 111 and 127 are further supported by, for example, original claim 36.

New claims 112 and 128 are further supported by, for example, page 16, lines 25-30 of the specification as filed.

New claims 113 and 129 are further supported by, for example, original claims 1 and 2.

New claims 114 and 130 are further supported by, for example, original claim 9.

New claims 115 and 131 are further supported by, for example, original claim 10.

New claims 116 and 132 are further supported by, for example, original claim 5.

New claims 117 and 133 are further supported by, for example, original claim 6.

New claims 118 and 134 are further supported by, for example, original claim 7.

New claims 119 and 135 are further supported by, for example, original claim 8.

New claims 120 and 137 are further supported by, for example, original claim 26.

New claims 121 and 138 are further supported by, for example, original claim 27.

New claims 122 and 139 are further supported by, for example, original claim 29.

New claims 123 and 136 are further supported by, for example, original claim 44.

New claims 124 and 140 are further supported by, for example, page 4, lines 4-7, of the specification.

New claims 125 and 141 are further supported by, for example, original claim 9.

New independent claim 142 is supported by, for example, original claims 35, 36 and 46.

No new matter has been introduced and entry of this Amendment is respectfully requested.

Information Disclosure Statement Filed August 24, 2005

Applicants respectfully request consideration of the references disclosed in the Information Disclosure Statement filed August 24, 2005. A duplicate copy of the PTO/SB/08, which accompanied the IDS filed August 24, 2005, is attached hereto for the Examiner's convenience.

Response to §103 Rejection

(1) At page 6 of the Office Action, the Examiner rejects claims 1-14, 17-25 and claims 75-91 under 35 USC §103(a) as being obvious over Lee et al. (1997) in view of Herman et al. (U.S. Patent 5,786,146).

Specifically, the Examiner contends that Lee shows that CpG sites -34 and -35 are not detectably methylated in normal tissue but are significantly methylated in 20 of 20 cancer specimens studied, and that two further restriction enzyme sites at -17/-18 and -13/-12 are methylated.

Thus, the Examiner believes that the one of ordinary skill in the art would have been motivated to use the methylation specific amplification taught by Herman to analyze methylation at CpG sites -34, -35, -17, -18, -12, and -13.

During the personal interview held on August 8, 2005, which was greatly appreciated, the Examiner indicated that the section 103 rejection would no longer be appropriate if the claims were amended to exclude those CpG sites taught by Lee to be abnormally methylated. (See Examiner's Interview Summary)

New independent claims 110, 126 and 142 recite detecting an abnormally methylated cytosine within a CpG site located within a region (the intragenic region) defined by and including nucleotides 1232 to 1942 (CpG sites +1 to +55) of the glutathione S-transferase (GST) Pi gene (SEQ ID NO: 60).[1]

Since the cited art does not teach abnormal methylation at any intragenic (non-promoter) site of the glutathione S-transferase (GST) Pi gene, nor abnormal methylation at any of CpG sites +1 to +55, independent claims 110, 126 and 142 are not *prima facie* obvious over the cited references.

Further, since the remaining claims directly or indirectly depend from claim 110 or claim 126, these dependent claims are patentable for at least the same reason as the independent claims.

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[1] Applicants reserve the right to prosecute claims directed to detecting methylation in the promoter region of the Gst-Pi gene in one or more divisional applications.

In view of the above, withdrawal of the section 103 rejection is believed to be appropriate and is respectfully requested.

Response to §112, First Paragraph Rejection

At page 3 of the Office Action, the Examiner rejects claims 1, 3-14, 19-21, 23, 26-29, and 77-109 under 35 U.S.C. §112, first paragraph, because SEQ ID NO: 60 is allegedly new matter.

Specifically, the Examiner contends that the reference to "SEQ ID NO: 60" in the claims, corresponding to the full sequence of the GST-Pi gene, is not supported by the original disclosure because the specification does not demonstrate a clear intent to incorporate it by reference using the root words "incorporate" and "reference" within the text.

This rejection is respectfully traversed.

New rule 37 CFR §1.57(b), which requires that the specification use the root words "incorporate" and "reference" to incorporate matter by reference, became effective in October of 2004. However, since the present application was filed prior to October of 2004 (e.g. in October of 2000), new rule 1.57(b) does not apply to this application.

During a telephone conversation between the undersigned attorney and Deborah Reynolds, a PTO Quality Assurance Specialist, Deborah Reynolds confirmed that new rule 1.57(b) is not retroactive. That is, the present application is governed by the rules for incorporation by reference that existed prior to new rule 1.57(b).

Therefore, MPEP §608.01(p) (as set forth in the May, 2004 edition) sets forth the appropriate guidelines for incorporating matter by reference in the present application.

It is respectfully submitted that the original specification clearly incorporates by reference Genbank Accession No. M24485, which is the GST-Pi sequence, and it is respectfully submitted that Genbank Accession No. M24485 is not a "mere reference" in the present specification.

Indeed, ***the entire application*** is directed to detecting methylation within this gene, as defined by Genbank Accession No. M24485. For example, the original claims of the application recite the GST-Pi sequence, which is defined in the specification at, for example, page 20, lines 8-32, to be Genbank Accession No. M24485. Further, the specification indicates that the numbering of nucleotides and sequences of the GST-Pi gene referred to therein is based on Genbank Accession No. M24485. Of course, the original figures (see particularly Figures 1 and 2) disclose much of Accession No. M24485.

Thus, Accession No. M24485 is clearly incorporated by reference into the specification as filed, and SEQ ID NO: 60 is not new matter.

Withdrawal of this rejection is respectfully requested.

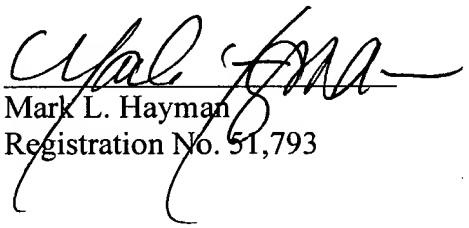
With respect to the Examiner's comments at page 5 of the Office Action, that the region of +9 to +55, in the context of diagnosing liver cancer, is also new matter, the Examiner's attention is directed to pages 9 and 23 of the specification, as well as original claims 9 and 46, which provide support for the same.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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